



## DEPARTMENT OF COMMERCE

### Patent and Trademark Office

[Docket No.: PTO-P-2022-0019]

### Extension of the Cancer Immunotherapy Pilot Program and Request for Comments

**AGENCY:** Patent and Trademark Office, Department of Commerce.

**ACTION:** Notice; request for comments.

**SUMMARY:** On June 29, 2016, the United States Patent and Trademark Office (USPTO) implemented the Cancer Immunotherapy Pilot Program in support of the White House's National Cancer Moonshot initiative, which sought to accelerate cancer research. The program permits patent applications pertaining to cancer immunotherapy to be advanced out of turn for examination. To date, over 835 petitions requesting participation in the pilot program have been filed, and over 615 patents have been granted under the program. In view of the continued interest in the Cancer Immunotherapy Pilot Program, as well as the White House's recent reignition of the National Cancer Moonshot initiative, the USPTO is extending the program, with all parameters remaining the same, until September 30, 2022. The USPTO is also in the process of deciding whether to expand the scope of the pilot program and may, additionally, further extend it (with or without modifications), depending on feedback from the participants and the public, additional continued interest, and the program's effectiveness.

**DATES:** Comments must be received by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] to ensure consideration.

*Pilot duration:* The Cancer Immunotherapy Pilot Program will continue to run until September 30, 2022. Therefore, petitions to make special under the Cancer Immunotherapy Pilot Program must be filed on or before September 30, 2022.

**ADDRESSES:** For reasons of Government efficiency, comments must be submitted through the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov). To submit comments via the portal, enter docket number PTO-P-2022-0019 on the homepage and click “Search.” The site will provide a search results page listing all documents associated with this docket. Find a reference to this notice and click on the “Comment Now!” icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in ADOBE® portable document format or MICROSOFT WORD® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal website ([www.regulations.gov](http://www.regulations.gov)) for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions.

**FOR FURTHER INFORMATION CONTACT:** For questions regarding this pilot program in general, please contact Susy Tsang-Foster, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, at 571-272-7711 or [susy.tsang-foster@uspto.gov](mailto:susy.tsang-foster@uspto.gov). For questions related to a particular petition, please contact Gary B. Nickol, Supervisory Patent Examiner, at 571-272-0835 or [gary.nickol@uspto.gov](mailto:gary.nickol@uspto.gov); or Brandon J. Fetterolf, Supervisory Patent Examiner, at 571-272-2919 or [brandon.fetterolf@uspto.gov](mailto:brandon.fetterolf@uspto.gov), both of Technology Center 1600.

**SUPPLEMENTARY INFORMATION:** On June 29, 2016, the USPTO published a notice for the implementation of the Cancer Immunotherapy Pilot Program. *See* Cancer Immunotherapy Pilot Program, 81 FR 42328 (Cancer Immunotherapy Notice). The pilot program was designed to support the global fight against cancer. The Cancer

Immunotherapy Notice indicated that an applicant could have an application advanced out of turn (accorded special status) for examination without meeting all the current requirements of the accelerated examination program set forth in item VIII of section 708.02(a) of the Manual of Patent Examining Procedure if the application contained at least one claim to a method of treating a cancer using immunotherapy and the applicant met other requirements specified in the Cancer Immunotherapy Notice.

The Cancer Immunotherapy Notice established that the pilot program would run for 12 months, beginning on June 29, 2016. Over the course of the pilot program, the USPTO has extended it through notices published in the Federal Register. The most recent notice extended the program until June 30, 2022. *See* Extension of the Cancer Immunotherapy Pilot Program, 85 FR 41570 (July 10, 2020). In view of the continued interest in the pilot program, the USPTO is hereby extending it through September 30, 2022. The extension will also allow the USPTO to continue its evaluation of the program. The requirements of the pilot program have not been modified.

Various stakeholders from around the world—including independent inventors, universities, research institutions, hospitals, medical centers, government agencies, and large and small companies—have filed petitions to participate in the pilot program. To date, over 835 petitions requesting participation have been filed, and over 615 patents have been granted under the pilot program.

The USPTO is currently deciding whether to expand the scope of the pilot program. The USPTO may further extend the program (with or without modifications), depending on feedback from the participants, additional continued interest, and the program's effectiveness. The USPTO welcomes public comment on these topics.

**Katherine K. Vidal,**

*Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

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